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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,968	08/26/2003	Helmut Borberg	07030.0004U2	7077
23859 7590 10/22/2007 NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			EXAMINER WIEST, PHILIP R	
			ART UNIT	PAPER NUMBER
			3761	
			MAIL DATE	DELIVERY MODE
			10/22/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/649,968	Applicant(s) BORBERG ET AL.	
	Examiner Phil Wiest	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 26 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/8/07 has been entered.

### ***Response to Amendment***

2. In the amendment filed 10/8/07, Applicant amended claim 1. Claims 1 and 2 are currently pending.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 & 2 are rejected under 35 U.S.C. 103(a) as obvious over

*"Plasmapheresis in the treatment of critical degree of ischaemia in diabetic and*

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*angiopathies of lower extremities*" (Georgadze et al.) in view of Malchesky et al.

(4,350,156), and further in view of Hunter (US 5,152,979)

Georgadze et al. teaches that plasmapheresis may be used for the treatment of ischemia in the lower extremities of diabetics. It is disclosed that the plasmapheresis corrects the biochemical and coagulation parameters of the blood and thereby preserves the extremity from amputation in most patients. Plasmapheresis will remove protein, as disclosed in the article (see chart & body of article). The treatment of blood via plasmapheresis as treatment for a person diagnosed with diabetic ischemia of the foot since the foot is met since a foot is obviously part of the lower extremity. Such treatment would be beneficial to preserve the foot from amputation. Georgadze et al. substantially teaches the invention as claimed, except for specifically teaching that the method to remove high molecular weight proteins and wherein the high molecular weight protein is lipoprotein cholesterol.

Malchesky et al. teaches of plasmafiltration of blood for the removal of high molecular weight proteins (for example 100,000 Daltons) such as cholesterol-lipid complexes (i.e. lipoprotein cholesterol). The removal of high molecular weight proteins has a variety of treatment benefits, such as treating various diabetes-related ailments and hyperviscosity syndromes (Column 1, Line 23 through Column 2, Line 8).

Hunter generally teaches that ischemia causes increased viscosity of blood and recognizes that increased whole blood viscosity is capable of causing serious circulatory disturbances (Column 3, Lines 63-68)

Therefore, it would have been obvious to one at the time of the invention, since the procedures of plasmapheresis of blood and plasmafiltration of blood are analogous fields of endeavor, to modify the method of Georgadze et al. to specifically remove high molecular protein, such as lipoprotein cholesterol, as taught by Malchesky et al. since both teach of removing protein from the blood to achieve a therapeutic result, such as returning blood to its normal viscosity. Hunter clearly teaches that ischemia causes impaired circulation because of blood hyperviscosity, and therefore provides motivation to prevent ischemia by Malchesky's method of viscosity control.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 1 and 2 have been considered but are moot in view of the new ground(s) of rejection.

Hunter teaches that it was well established in the art at the time of invention that ischemia causes an increase in blood viscosity. Malchesky clearly discloses a system that is capable of treating hyperviscosity of blood and various diabetic symptoms by removing lipoprotein cholesterol.

Therefore, as stated above, it is the examiner's opinion that it would have been fully within the scope of one of ordinary skill in the art at the time of invention to modify the method of plasmafiltration of the lower extremities of Georgadze with the selective removal of high density proteins in order to improve blood viscosity, thereby improving blood circulation through the targeted area.

Additionally, regarding applicant's amendment to claim 1, it is the examiner's opinion that the steps of "removing" and "filtering" are substantially the same.

**Conclusion**

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW  
10/18/07

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

